Supreme Court, U.S.
FILED
AUG 28 1991
OFFICE OF THE CLERK

No. 91-13

IN THE

Supreme Court of the United States

OCTOBER TERM, 1991

GENETICS INSTITUTE, INC.,
AND CHUGAI PHARMACEUTICAL CO., INC.,
Petitioners,

v.

AMGEN, INC.,
Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY TO BRIEF IN OPPOSITION

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REPLY TO BRIEF IN OPPOSITION

The Court of Appeals has expressly acknowledged that its decision resolves an important legal question of first impression, and an unusually knowledgeable array of *amici curiae* who have no interest in the underlying patent dispute have filed briefs expressing their view that this decision constitutes an important and unfortunate change in the law. Nevertheless, the Brief in Opposition claims that the petition for writ of certiorari does not "even [present] a legal issue." Brief in Opposition (Br.Opp.) at 1. Respondent accomplishes this feat by mischaracterizing the petition and by misstating what the lower courts have held.

1. Respondent attributes to petitioners the claim that, prior to the decision below, cell deposits had always been required for patents involving natural organisms, Br.Opp. 9, 13 n.6, and that, because of the decision below, such deposits will never be required for genetic engineering patents, Br.Opp. 2, 13, 14 n.7. Petitioners say no such thing.

Of course best mode requirements may often be satisfied by written descriptions. At stake here are the legal standards that determine when such written descriptions suffice under 35 U.S.C. § 112, and when only cell deposits will do. Respondent seeks to use a straw man to distract attention from the Federal Circuit's acknowledged rewriting of those legal standards. That shift in standards has been noticed by a sophisticated and disinterested group of *amici*. According to the nation's premier depository of scientific cultures, the Federal Circuit's newly announced legal standard has dramatically reduced the pressure on genetic engineers to place samples of their cell lines in public depositories, and thereby "has already begun to impede the purposes of the patent regime's deposit rules by introducing uncertainty and disuniformity into deposit requirements." Brief *Amicus Curiae* of the American Type Culture Collection (ATCC) at 4; *see also id.* at 8, 9-10.

2. Respondent invokes a 1990 Patent Office regulation that "rejects a deposit requirement" where "written disclosure is adequate," to suggest that the "ruling below . . . has no significance for patent applications beyond the one at issue in this case." Br.Opp. 14 & n.8 (citing 37 C.F.R. § 1.802(b) (1990)). The suggestion is groundless, for as the Federal Circuit itself recognized in 1991, *see* Petition Appendix A21-A22, this 1990 regulation changed nothing: it was a mere codification expressly designed to "continue . . . long-standing practices of the [Patent] Office and judicially developed principles of patent law." 53 Fed.Reg. 39420 (Oct. 6, 1988) (proposing the regulation adopted in 1990). Inspection of the very words respondent quotes from the regulation confirms that the "new" deposit rule simply paraphrased the legal standard that had been in place ever since *Application of Argoudelis*, 434 F.2d 1390 (C.C.P.A. 1970). Under this enduring standard, as respondent elsewhere concedes, a deposit of biological material was required to supplement a written disclosure whenever "written disclosure [would] not permit *reproduction* of the invention without undue experimentation." Br.Opp. 10 (emphasis added). This case is made *more* worthy of the Court's attention, not less, by the fact that the Federal Circuit has diluted the deposit standard ("reproducibility") that the Patent Office embraced for two decades.

3. In modifying this long-settled deposit standard, the Federal Circuit addressed what it described as a "question of first impression concerning the best mode requirement for patents involving novel genetically engineered biological subject matter" (A19), and held that a deposit of a unique newly engineered cell is not necessarily required of a patent applicant — even if that cell is not publicly available, does not exist anywhere else in the world except in the patentee's laboratory, and *cannot be reproduced* from the written description alone.[1]

[1] Respondent contends that the court below was mistaken in thinking its decision novel, for, we are told, the Federal Circuit had ruled on the issue on

4. This is the holding that creates new law — and alarmingly bad law at that, as all of the *amici* painstakingly explain.[2] Rather than defending this modification in the legal standard, respondent hopes to obscure it by misrepresenting what both of the courts below *expressly found* with respect to reproducibility. Respondent asserts that "the written specification has been found by two courts to have adequately disclosed the best mode of the invention and to have *allowed that best mode to be readily reproduced*." Br.Opp. 9-10 (emphasis added). Later, respondent repeats that "both lower courts explained . . . that here the written description and publicly available starting materials *readily enabled reproduction of not just any mode of the invention but rather the best mode of the invention*," Br.Opp. 13 (emphasis added).

This is simply not so. Both the district court and the Federal Circuit in fact agreed that Amgen's best mode cells were *irreproducible* without access to a deposit, no matter how much

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previous occasions. Br.Opp. 13 n.6. In fact, neither of the cases cited by respondent even addressed the deposit standard under § 112's best mode requirement, and one of them did not involve any best mode issue at all. Respondent elsewhere cites two additional cases where the Federal Circuit supposedly addressed this issue of first impression, Br.Opp. 11, but those cases actually confirm that the decision below has rewritten prevailing Patent Office rules. *In re Wands*, 858 F.2d 731 (Fed.Cir. 1988), did not present the issue of whether a best mode deposit is required — for there the inventor had deposited his best mode hybridoma cell as part of his patent application. *Id.* at 736. Only the enablement of other generic patent claims was at issue on appeal. And in *Ex parte Goeddel*, 5 USPQ2d 1449 (PTO Bd. of Pat.App. and Interferences), the Patent Office rejected a § 112 challenge precisely because the "microorganisms employed by appellants *to produce* the claimed polypeptide are known materials on deposit with the American Type Culture Collection." *Id.* at 1450 (emphasis in original).

Petitioners contend that Amgen was likewise required to deposit its EPO-producing cells because they are unavailable and irreproducible without a deposit; whether to excuse such a failure to deposit, on a basis unique to genetically engineered cells, was the issue of first impression that the court below resolved.

[2] Even the article respondent cites for the proposition that the decision below did nothing new, *see* Br.Opp. at 13-14, in fact agrees that the Federal Circuit resolved a question "of first impression," although it referred to established principles in doing so. *See* Baechtold, *et al.*, *Property Rights in Living Matter: Is New Law Required?*, 68 DENV.L.REV. 141, 169 (1991).

time and energy was invested: "*no scientist could ever duplicate exactly the best mode used by Amgen.*" (A22) (emphasis added). *See* Pet. 16-18, 20-23.[3] Moreover, the Federal Circuit itself recognized that it was enacting a new and lower standard for bioculture deposits with respect to genetically engineered cells, because it conceded that this lack of reproducibility from the written disclosure alone would have mandated the deposit of naturally occurring cells. (A19-A21). *See* Pet. 18-22. Respondent defends judicial power to "fashion" patent rules to reflect a distinction between "natural organisms" and "genetically-engineered organisms," Br.Opp. 16, but *Diamond* v. *Chakrabarty*, 447 U.S. 303, 307, 317-318 (1980), held that such lines are beyond the purview of the federal judiciary to legislate.

5. Respondent's attempt to explain away the Federal Circuit's decision as somehow leaving the reproducibility standard intact cannot succeed because it is built entirely on this central misconception of the opinions below. Indeed, it seems that some of the *amici* anticipated this fallacious line of argument. *See* Brief *Amici Curiae* of Professor Roger Sperry, *et al.* at 7-8. No less authoritative a body than the American Type Culture Collection, which is directed by representatives of all the major North American scientific societies and which assists the Patent Office in writing its deposit rules, has noted the significance of the sudden relaxation in deposit requirements wrought by the decision below, and has explained the resulting harm to scientific research that is already being felt. Brief *Amicus Curiae* of the ATCC at 8-11. *See also* Brief *Amici Curiae* of the American Foundation for AIDS Research, *et al.* at 9-11.

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[3] Respondent also repeatedly represents that the patent's written disclosure was found adequate to enable others to produce transfected host cells "with equivalent levels of EPO production." Br.Opp. 3, 4, 5. This, too, is untrue. What the testimony actually revealed, and what the courts actually found, was that one could produce *some* sort of host cell that "could be worse in terms of EPO production." (A20). By definition, such a patent specification discloses not the best mode of the invention, but an inferior mode.

6. It is no answer for respondent to dismiss the Federal Circuit's decision as unworthy of this Court's attention because the court below simply engaged in a fact-bound, case-specific inquiry: it is precisely our point, and that of the *amici*, that the Federal Circuit *engaged in the wrong inquiry* — that it concocted a "watered-down, . . . case-by-case" disclosure standard specifically for genetically engineered cell deposits that will work great mischief for the progress of science and medicine. Brief *Amici Curiae* of Professor Roger Sperry, *et al.* at 8. The previous rule required cell deposits whenever the best mode cells were irreproducible from the written disclosure alone. That involved a fact inquiry of sorts, but one proceeding under a clear governing legal standard. The Federal Circuit has replaced that bright line of irreproducibility with a vague, *ad hoc* standard allowing patentees to avoid deposits of genetically engineered cells whenever the written description enables others to make *something like* the best mode of the invention. *See* Pet. at 17-18; *Amicus Brief* of the ATCC at 9-10.

The *amici* explain how the fact-intensive uncertainty of this new standard will discourage the bioculture deposits that are vital to the advancement of biomedical science by encouraging inventors to gamble that they can get a patent without making a deposit. If a patent applicant thinks he has a chance of receiving a patent monopoly while keeping his best mode cell line as a trade secret, he has little incentive to place a sample of that cell line in a culture depository. *See Amicus* Brief of the ATCC at 8-10; *Amici* Brief of the American Foundation for AIDS Research *et al.* at 10-11; *Amici* Brief of Professor Roger Sperry, *et al.* at 8.[4] The appeals court's newly developed

[4] Respondent's contention that "the precision of recombinant DNA technology would *under certain circumstances* permit written disclosure to satisfy the requirements of § 112 without a deposit," Br.Opp. at 12 n.5 (emphasis added), is beside the point, because this is not such a hypothetical case. Here the Federal Circuit agreed that the technology was not that precise, and therefore it found that Amgen's best mode cell line was irreproducible without access to a cell deposit. Moreover, respondent's own authorities concede the need

ad hoc "rule" is thus an ill-conceived judicial innovation — and it is one that neither the Patent Office nor any other circuit court is in a position to undo.

7. Respondent belittles the deposit requirement as unworthy of judicial solicitude because it is only a "rule" and "is not mandated by the language of the statute itself." Br.Opp. 15. But that mere "rule" was promulgated by the Commerce Department's Patent Office pursuant to a mandate Congress gave to that executive agency, *not* to the federal judiciary, and the courts are bound to respect it. *See Chevron, USA, Inc.* v. *NRDC, Inc.*, 467 U.S. 837, 865-66 (1984).[5]

8. Respondent does not contest that the decision below, for the first time since 1793, *see* Pet. at 14 & n.4, deems undisputed evidence of a patentee's active concealment of the best mode to be "irrelevant" as a matter of law. (A23). The Patent Office

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for deposits when the best mode cells cannot be "reproduced with certainty on the basis of the written disclosure." Meyer, *Problems and Issues in Depositing Microorganisms For Patent Purposes*, 65 J. PAT. OFF. SOC'Y 455, 460 (1983). *See also id.* at 460 ("If the application discloses and claims a particular plasmid or microorganism strain . . . then the particular plasmid or strain will probably have to be deposited to comply with the best mode requirements of the first paragraph of 35 U.S.C. § 112."); Hampar, *Patenting of Recombinant DNA Technology: The Deposit Requirement*, 67 J. PAT. OFF. SOC'Y 569, 586, 591 (1985) (when a biological invention involves random processes, "shotgun" procedures, "the deposit requirement may be invoked without further consideration"; variability and randomness are "inherent in the art of recombinant DNA technology"); Baechtold, *et al.*, *Property Rights in Living Matter: Is New Law Required?*, 68 DENV.L.REV. 141, 168 (1991) ("cells cannot be made available by verbal description, and processes carried out in living systems are subject to greater variability so that a written description does not guarantee that the reader will achieve an exact replication of what the patentee got.").

[5] Respondent dismisses the grant of executive authority in 35 U.S.C. § 114 as dealing exclusively with models to show that machines are operable. Br.Opp. 15 n.9. This is incorrect. The second paragraph of § 114 expressly authorizes the Patent Office to "require the applicant to furnish specimens or ingredients for the purpose of inspection or experiment" "[w]hen the invention relates to a composition of matter" (A240), and *Chakrabarty* held that a genetically engineered microorganism is a patentable "composition of matter." 447 U.S. at 309. Section 114 has been invoked to authorize Patent Office demands for culture deposits of microorganisms by patent applicants. *See Feldman* v. *Aunstrup*, 517 F.2d 1351, 1354 (C.C.P.A. 1975), *cert. denied*, 424 U.S. 912 (1976).

initially rejected Amgen's patent for lack of adequate deposits, *see* Pet. 24 & n.14, and Amgen went to great lengths to distract the patent examiner (and to cheat scientists and the public) by depositing worthless cell material instead of its EPO-producing host cells.[6] Respondent's own authorities confirm that what must be deposited in such cases are the *actual hormone- or protein-producing cells themselves*, if those cells are novel and irreproducible from the written patent specification alone.[7] No previous decision of this Court has provided guidance on the best mode and concealment issues of § 112. Because the decision below is already encouraging patent applicants to conceal their cell lines and hoard them as trade secrets, with adverse consequences for both science and society, see *Amicus* Brief of the ATCC at 10-11, this issue deserves the Court's prompt attention.[8]

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[6] Indeed, respondent continues to insist that "[e]ach of the deposits was made for the purpose of providing access to potentially *unique* starting materials." Br.Opp. 15 n.9 (emphasis in original). Yet even the Federal Circuit noted that Amgen's deposits were "worthless cell material" (A23) and the *amici* confirm that the supposedly "unique" materials contained in Amgen's original deposits with the ATCC were simple yeast available from any bakery, and simple bacteria available from any sample of human feces. *See Amici* Brief of the American Foundation for AIDS Research, *et al.* at 10 n.5.

[7] *See, e.g., Ex parte Goeddel*, 5 USPQ2d 1449, 1450 (PTO Bd. of Pat.App. and Interferences 1987) (rejecting § 112 challenge because of deposit of actual microorganisms used to produce interferon); *Tabuchi* v. *Nubel*, 559 F.2d 1183, 1187-88 (C.C.P.A. 1977) (rejecting § 112 challenge because of deposit in ATCC of actual yeast strain used to produce citric acid); *Merck & Co.* v. *Chase Chemical Co.*, 273 F.Supp. 68, 76 (D.N.J. 1967) (rejecting § 112 challenge because of deposit of actual bacteria used to produce vitamin); *In re Lundak*, 773 F.2d 1216, 1217-18 (Fed.Cir. 1985) (endorsing deposit of actual cell line used to produce immunoglobulins); *Feldman* v. *Aunstrup*, 517 F.2d 1351, 1352, 1355 (C.C.P.A. 1975) (rejecting § 112 challenge because of deposit of actual microbes used to produce enzyme), *cert. denied*, 424 U.S. 912 (1976); *Application of Argoudelis*, 434 F.2d 1390, 1390-91, 1392 (C.C.P.A. 1970) (rejecting § 112 challenge because of deposit of actual microbes used to produce antibiotic).

[8] Respondent's attempt to portray the results of the Federal Circuit's decision as innocuous and to portray petitioners as misrepresenting an article by noted patent authority Albert Halluin, Br.Opp. 14 n.7, falls flat in light of Mr. Halluin's appearance here as counsel for *amicus* ATCC, urging this Court to grant certiorari. *See Amicus* Brief of the ATCC at 10 & n. 10.

9. This case merits plenary review for another reason as well. Respondent seems to endorse the Federal Circuit's "salami-slicing" approach to the invalidation of genetic engineering patent claims in the face of a best mode violation, which is a departure from the way § 112 is applied in all other fields of technology. *See* Pet. 25-26 & n.15.[9] Respondent does not contest petitioners' explanation of how the Federal Circuit's new approach will render the best mode requirement a virtual dead letter in the area of recombinant DNA. Its only defense is the self-contradicting notion that "the host cells are entirely unrelated to the DNA sequence," even though respondent does not claim that the isolated DNA sequence for EPO has any use other than to make host cells to produce EPO. Br.Opp. 17. This approach virtually guarantees that deposits of host cells will not be made in the future — why should they be, if a patentee is allowed, *even in the face of a conceded § 112 violation*, to retain a monopoly on the DNA sequence whose only utility is making host cells, and without which no one else could make such cells? This is an additional reason to grant certiorari, *not* a reason to deny it.

10. Finally, with respect to the enablement of Genetics Institute's purified hormone ('195) patent, respondent tries to scare the Court by adverting to the huge size of the trial court record. Br.Opp. 19. But there is no need for this Court ever to reevaluate that evidence or to go behind the district court's written findings, because the whole point is that the Federal Circuit should never have done so in the first place. No inquiry beyond a comparison of the two opinions below is necessary in order to conclude that the Federal Circuit ignored the district court's findings of historical fact and substituted its own, in violation of Fed.R.Civ.P. 52(a) and the decisions of this Court. Pet. 27-29. Indeed, Amgen does not actually deny that this is just what the Federal Circuit did — it merely notes that enablement is a legal question and acts as if the Federal Circuit were

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[9] Respondent's only contrary authority, Br.Opp. 17, is a case petitioners have already distinguished, Pet. 25-26 n.15.

therefore free to retry the facts underlying that question, especially since the Federal Circuit, we are told, got the evidence right while the district court got it wrong. Br.Opp. 18-19.[10] This Court has previously had to reign in appellate judges who usurp the trial court's role, and such supervision is once again in order here.

We readily concede that, standing alone, this second question might be unworthy of this Court's attention. In the past, *see, e.g., Anderson* v. *City of Bessemer*, 470 U.S. 564 (1985), this Court has taken the opportunity presented by other important questions to remind the courts of appeals of their proper role under Rule 52(a). Such an exercise of jurisdiction here would have the advantage of placing before the Court all aspects of this dispute.

CONCLUSION

If petitioners were the only ones who perceived that the decision below has rewritten the deposit rules enforcing the best mode requirement of § 112 and has thereby jeopardized the vitally important public deposit regime, perhaps respondent would be justified in relying so heavily on this Court's general reluctance to review patent cases. But since even the Federal Circuit recognized that it was deciding a question of first impression, and since its decision has alarmed leading scholars,

[10] Even then, respondent merely recites the Federal Circuit's new findings about the alleged nonenablement of petitioner's patent, Br.Opp. 19-20, totally ignoring the uncontested fact that those findings rely on evidence of various unsuccessful efforts to purify EPO — evidence that the district court expressly rejected as meaningless because there was no proof whatsoever that the process set forth in Genetics Institute's purified hormone patent had been used in any of those efforts. (A185-A186).

major research foundations, and the entire scientific community — as represented by the nation's premier scientific culture archive — petitioners hope that respondent's reliance is misplaced. A writ of certiorari should be granted.

Respectfully submitted,

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